

Claims

[c1] A medical device, comprising:

an imaging element for subcutaneous placement in a tissue mass to identify an area of interest in the tissue mass; and

a guide element connected to the imaging element and having a separable portion;

wherein when the imaging element is placed within the tissue mass, at least part of the guide element extends exteriorly of the tissue mass to permit the locating of the area of interest, and when the separable portion is separated from the guide element, no part of the guide element extends exteriorly of the tissue mass.

[c2] The medical device according to claim 1, wherein the separable portion comprises the entire guide element.

[c3] The medical device according to claim 1, wherein the imaging element can be imaged by at least one of the following imaging techniques:

- x-ray,
- ultrasound,
- magnetic resonance imaging (MRI),
- computer assisted tomography (CAT),
- mammography,
- fluoroscopy,
- Doppler,
- other roentgenological imaging methods,
- visualization, and
- detection of emission.

- [c4] The medical device according to claim 1, wherein the imaging element comprises a portion that is one of bioabsorbable or non-bioabsorbable.
- [c5] The medical device according to claim 4, wherein the guide element is bioabsorbable.
- [c6] The medical device according to claim 4, wherein the imaging element comprises a first portion that is non-bioabsorbable and a second portion that is bioabsorbable.
- [c7] The medical device according to claim 6, wherein the first portion comprises titanium.
- [c8] The medical device according to claim 6, wherein the second portion comprises collagen.
- [c9] The medical device according to claim 1, wherein the imaging element further comprises at least one extension.
- [c10] The medical device according to claim 9, and further comprising a bioabsorbable element mounted to the extension.
- [c11] The medical device according to claim 10, wherein the bioabsorbable element encapsulates at least a portion of the extension.
- [c12] The medical device according to claim 1, wherein the imaging element defines a guide element opening through which the guide element passes.
- [c13] The medical device according to claim 12, wherein the imaging element comprises a loop that defines the guide element opening.
- [c14] The medical device according to claim 13, wherein the guide element is a

filament.

- [c15] The medical device according to claim 14, wherein the filament is made from suture material.
- [c16] The medical device according to claim 15, wherein the filament is a metal wire.
- [c17] The medical device according to claim 1, and further comprising a holder mounted to a portion of the guide element exterior of the tissue mass to hold the position of the guide element relative to the tissue mass.
- [c18] The medical device according to claim 1, and further comprising a releasable connection connecting the guide element to the imaging element to form the separable portion.
- [c19] The medical device according to claim 18, wherein the releasable connection comprises a threaded coupling.
- [c20] The medical device according to claim 18, wherein the releasable connection is a weldment.
- [c21] The medical device according to claim 18, wherein the releasable connection is a severable portion of the guide element.
- [c22] The medical device according to claim 18, wherein the releasable connection is a discontinuity in the guide element.
- [c23] The medical device according to claim 1, and further comprising a gripping element attachable to the guide element for separating the guide element from the imaging element.
- [c24] The medical device according to claim 1, wherein the imaging device is releasable

to permit the repositioning of the medical device in the tissue mass.

- [c25] The medical device of claim 24 wherein the imaging device comprises at least one flexible hook.
- [c26] The medical device according to claim 1, wherein the guide element is a filament.
- [c27] The medical device according to claim 23, wherein the filament comprises a length of wire.
- [c28] The medical device according to claim 23, wherein the filament comprises a length of suture material.
- [c29] The medical device according to claim 1, wherein the guide element comprises a bioabsorbable material.
- [c30] A method for localizing and marking an area of interest in a tissue mass, comprising the steps of:
providing a medical device comprising an imaging element and a guide element connected to the imaging element; and
inserting the medical device into the tissue mass so that at least part of the guide element extends exteriorly of the tissue mass.
- [c31] The method according to claim 30, and further comprising the step of removing at least a portion of the guide element so that no portion of the guide element extends exteriorly of the tissue mass.
- [c32] The method according to claim 30, and further comprising the step of unthreading the at least a portion of the guide element to remove the at least a portion of the guide element.
- [c33] The method according to claim 30, and further comprising the step of pulling the

guide element to remove at least a portion of the guide element.

- [c34] The method according to claim 33, a wherein the removing step comprises cutting the guide element.
- [c35] The method according to claim 33, wherein the removing step comprises removing the entire guide element from the tissue mass.
- [c36] The method according to claim 33, wherein the removing step comprises separating at least a portion of the guide element from the imaging element.
- [c37] The method according to claim 36, wherein the removing step comprises removing the entire guide element from the tissue mass.
- [c38] The method according to claim 33, wherein the removing step comprises separating the guide element from the imaging element at a spot weld.
- [c39] The method according to claim 34, wherein the removing step further comprises removing a cut portion of the guide element.
- [c40] The method according to claim 30, and further comprising the step of locating the imaging element by an imaging technique.
- [c41] The method according to claim 40, and further comprising the step of removing the at least a portion of the guide element after the locating of the imaging element.
- [c42] The method according to claim 41, and further comprising the step of locating the area of interest in the tissue mass for surgical excision by following the guide element.
- [c43] A delivery apparatus for the percutaneous placement of a medical device at an

area of interest in a tissue mass to facilitate subsequent determination of the area of interest, comprising:

an introducer, comprising:

a cannula defining a lumen and having a proximal end, a distal end forming an insertion tip, and an expulsion opening near the insertion tip;

a stylet having a distal end slidably received within the lumen, and when the delivery apparatus is in a ready position, the distal end is spaced inwardly from the insertion tip to form a recess between the distal end and the insertion tip; and a medical device positioned within the recess, comprising:

an imaging element for subcutaneous placement in a tissue mass to identify an area of interest in the tissue mass; and

a guide element connected to the imaging element and having a separable portion; and

wherein the cannula is inserted into the tissue mass such that when the stylet is advanced into the recess, the medical device is expelled through the expulsion opening into the tissue mass, and when the cannula is withdrawn from the tissue mass, the imaging element is placed within the tissue mass at the area of interest, and at least part of the guide element extends exteriorly of the tissue mass, and when the separable portion is separated from the guide element, no part of the guide element extends exteriorly of the tissue mass.

- [c44] The delivery apparatus according to claim 43, and further comprising a handle to which the proximal end of the cannula is mounted.
- [c45] The delivery apparatus according to claim 44, wherein the handle, cannula, stylet, and medical device are operably coupled such that they form a self-contained marking apparatus that can be easily and conveniently handled by a user to effect operation of the delivery apparatus to expel the medical device.

- [c46] The delivery apparatus according to claim 45, wherein the separable portion comprises the entire guide element.
- [c47] The delivery apparatus according to claim 45, wherein the imaging element can be imaged by at least one of the following imaging techniques:
 - x-ray,
 - ultrasound,
 - magnetic resonance imaging (MRI),
 - computer assisted tomography (CAT),
 - mammography,
 - fluoroscopy,
 - Doppler,
 - other roentgenological imaging methods,
 - visualization, and
 - detection of emission.
- [c48] The delivery apparatus according to claim 45, wherein the imaging element comprises a portion that is one of bioabsorbable or non-bioabsorbable.
- [c49] The delivery apparatus according to claim 48, wherein the guide element is bioabsorbable.
- [c50] The delivery apparatus according to claim 48, wherein the imaging element comprises a first portion that is non-bioabsorbable and a second portion that is bioabsorbable.
- [c51] The delivery apparatus according to claim 45, wherein the imaging element further comprises at least one extension.
- [c52] The delivery apparatus according to claim 51, and further comprising a

bioabsorbable element mounted to the extension.

- [c53] The delivery apparatus according to claim 45, wherein the imaging element defines a guide element opening through which the guide element passes.
- [c54] The delivery apparatus according to claim 53, wherein the imaging element comprises a loop that defines the guide element opening.
- [c55] The delivery apparatus according to claim 54, wherein the guide element is a filament.
- [c56] The delivery apparatus according to claim 45, and further comprising a holder mounted to a portion of the guide element exterior of the tissue mass to hold the position of the guide element relative to the tissue mass.
- [c57] The delivery apparatus according to claim 45, and further comprising a releasable connection connecting the guide element to the imaging element to form the separable portion.
- [c58] The delivery apparatus according to claim 57, wherein the releasable connection comprises a threaded coupling.
- [c59] The delivery apparatus according to claim 57, wherein the releasable connection is a weldment.
- [c60] The delivery apparatus according to claim 57, wherein the releasable connection is a severable portion of the guide element.
- [c61] The delivery apparatus according to claim 57, wherein the releasable connection is a discontinuity in the guide element.
- [c62] The delivery apparatus according to claim 45, wherein the guide element is a

filament.

- [c63] The delivery apparatus according to claim 62, wherein the filament comprises a length of wire.
- [c64] The delivery apparatus according to claim 62, wherein the filament comprises a length of suture material.
- [c65] The delivery apparatus according to claim 45, wherein the guide element comprises a bioabsorbable material.
- [c66] The delivery apparatus according to claim 45, and further comprising a gripping element attachable to the guide element for separating the guide element from the imaging element.
- [c67] The delivery apparatus according to claim 45, wherein the imaging device is releasable to permit the repositioning of the medical device in the tissue mass.
- [c68] The delivery apparatus of claim 67 wherein the imaging device comprises at least one flexible hook.